K112120

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

JAN 24 2013

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Date the Summary was Prepared:	January 24, 2013
Name of the Device	D-Dimer Assay Kit D-Dimer Assay Calibrator Set D-Dimer Assay Control Set
Trade Name:	Diazyme D-Dimer Assay Kit Diazyme D-Dimer Assay Calibrator Set Diazyme D-Dimer Assay Control Set
Common/Usual Name	D-Dimer Assay
Device Classification Name	D-Dimer Test System
Product code:	GHH Fibrin Split Products DAP Fibrinogen and Fibrin Split Products, Antigen, Antiserum, Control JIT Calibrator, Secondary
Panel:	Hematology (81)
Submission Type	510k
Regulation Number	21CFR 866.7320

Device Class	Class II
Predicate Device:	Roche TINA-QUANT D-DIMER SYSTEM (k062203)
Manufacturing Address	Diazyme Laboratories 12889 Gregg Court Poway, CA 92064 USA
Establishment Registration	2032900

Description of the Device:

Summary
Thrombus formation is normally followed by an immediate fibrinolytic response. The resultant generation of plasmin causes the release of fibrin degradation products (predominantly containing D-Dimer) into the circulation.

Assay Principle
Diazyme's D-Dimer Assay is based on a latex enhanced immunoturbidimetric assay. D-Dimer proteins in the sample bind to the specific anti-D-Dimer antibody, which is coated on latex particles, and causes agglutination. The degree of the turbidity caused by agglutination can be measured optically and is proportional to the amount of D-Dimer in the sample. The instrument calculates the D-Dimer concentration of a patient specimen by interpolation of the obtained signal of a 6-point calibration curve.

Indications for Use:
The D-Dimer Assay is for the quantitative determination of fibrinogen/fibrin degradation products (D-Dimer) in human plasma. Measurement of D-Dimer is used as an aid in detecting the presence of intravascular coagulation and fibrinolysis. For *in vitro* diagnostic use only.

The Diazyme D-Dimer Calibrator Set is intended for use of the calibration of the Diazyme D-Dimer Assay only. For *in vitro* diagnostic use only.

The Diazyme D-Dimer Control Set is intended for use as quantitative quality controls for the Diazyme D-Dimer Assay only. For *in vitro* diagnostic use only.

Table 1 Summary of Assay Kit Components

Roche Tina-Quant D-Dimer k062203	Diazyme D-Dimer Assay
Reagent 1 buffer solution, ready to use Reagent 2 Anti-D-Dimer latex suspension (0.15%) in pH 7.2 buffer matrix	Reagent 1 100 mM Tris-buffer solution with 0.09% sodium azide, ready to use Reagent 2 Suspension of latex particles (< 0.2%) coated with mouse monoclonal anti-human D-Dimer with 0.09% sodium azide, ready to use. Calibrators Five lyophilized calibrators, one saline calibrator
Calibrator set	Calibrator set
1 x 2.5 mL Diluent, Cal 1 1 x 0.5 mL Calibrator 6	Saline (as cal 0, not provided) 1 x 1.0 mL Calibrator 1 1 x 1.0 mL Calibrator 2 1 x 1.0 mL Calibrator 3 1 x 1.0 mL Calibrator 4 1 x 1.0 mL Calibrator 5
Control Set serum based	Control Set serum based
1 x 0.5mL Control 1 1 x 0.5mL Control 2	1 x 1.0mL Control 1 1 x 1.0mL Control 2

Comparison of new device to predicate: The charts below identify similarities and differences between the predicate device and the Diazyme D-Dimer Assay.

Indications for Use

Roche Tina-Quant D-Dimer k062203	Diazyme D-Dimer Assay	Equivalency
For the in vitro quantitative determination of fibrin degradation products including D-Dimer and X-oligomers. Aid in detecting the presence and degree of intravascular coagulation and fibrinolysis and in monitoring therapy for disseminated intra vascular coagulation. In conjunction with a non-high clinical	The Diazyme D-Dimer Assay is for the quantitative determination of fibrinogen/fibrin degradation products (D-Dimer) in human plasma. Measurement of D-Dimer is used as an aid in detecting the presence of intravascular coagulation and fibrinolysis. For in vitro diagnostic use only.	Same

probability assessment, a normal (<0.5 µg FEU/mL) result excludes deep vein thrombosis (DVT) and pulmonary embolism (PE) with high sensitivity.		

Principle

Roche Tina-Quant D-Dimer k062203	Diazyme D-Dimer Assay	Equivalency
Latex particles of uniform size are coated with monoclonal antibodies ($F(ab')_2$ fragments) to the D-Dimer epitope. The antigen/antibody complexes produced by the addition of samples containing D-Dimer lead to an increase in the turbidity of the test reactants. The change in absorbance with time is dependent on the concentration of D-Dimer epitopes in the sample.	Diazyme D-Dimer Assay is based on a latex enhanced immunoturbidimetric assay. D-Dimer proteins in the sample bind to the specific anti-D-Dimer antibody, which is coated on latex particles, and causes agglutination. The degree of the turbidity caused by agglutination can be measured optically and is proportional to the amount of D-Dimer in the sample. The instrument calculates the D-Dimer concentration of a patient specimen by interpolation of the obtained signal of a 6-point calibration curve.	Same

Test Objective

Roche Tina-Quant D-Dimer k062203	Diazyme D-Dimer Assay	Equivalency
For the *in vitro* quantitative determination of D-Dimer in citrated or li-heparin plasma.	For the *in vitro* quantitative determination of D-Dimer in citrated plasma.	Same

Type of Test

Roche Tina-Quant D-Dimer k062203	Diazyme D-Dimer Assay	Equivalency
Quantitative	Quantitative	Same

Specimen Type

Roche Tina-Quant D-Dimer k062203	Diazyme D-Dimer Assay	Equivalency

Human citrated or li-heparin plasma.	Human citrated plasma.	Same

Product Type

Roche Tina-Quant D-Dimer k062203	Diazyme D-Dimer Assay	Equivalency
Assay reagent kit, calibrator kit, quality control kit.	Assay reagent kit, calibrator kit, quality control kit.	Same

Performance

Roche Tina-Quant D-Dimer k062203	Diazyme D-Dimer Assay
Working Range: 0.15-9 µg/mL FEU D-Dimer Precision: CV% of 0.8 – 8.3% Methods Comparion (vs Asserachrom D-Dimer k862156): Correlation Coefficient: 0.775 Slope/Intercept: y = 1.03/-0.11	Linear Range: 0.15-8 µg/mL FEU D-Dimer Precision: CV% of 1.4% - 6.2% Methods Comparion (vs. Roche Tina-Quant D-Dimer k062203): Correlation Coefficient: 0.939 Slope/ y Intercept: y = 0.979 /-0.10

Calibrator Comparison

Roche D-Dimer Calibrator	Diazyme D-Dimer Calibrator	Equivalency
Separately packaged lot specific calibrator kit. Lyophilized.	Separately packaged lot specific calibrator kit. Lyophilized.	Same

Control Comparison

Roche D-Dimer Control I/II	Diazyme D-Dimer Control	Equivalency
Separately packaged quality control kit designed for specific assay. Lyophilized.	Separately packaged quality control set designed for specific assay. Lyophilized.	Same

Performance Testing Summaries:

The data (precision, method comparison, linearity, LOB/LOD/LOQ and interference) determined using Roche Modular P is given below.

Precision
Internal Study

The precision of the Diazyme D-Dimer Assay was evaluated according to Clinical Laboratory Standards Institute EP5-A guideline.

In the study, three levels of pooled citrated plasma specimens containing 0.60 μg/mL, 2.41 μg/mL and 5.88 μg/mL FEU, respectively. The low plasma sample was unaltered. The other two plasma samples were spiked with D-Dimer stock solution to targeted concentrations and assayed. Three levels of D-Dimer controls containing 0.97, 2.99 and 7.47 μg/mL FEU, respectively were also tested with 2 runs per day with duplicates over 20 working days with three lots of reagent and three lots of calibrators. The combined results are shown below:

Plasma Samples Within Run Precision

	Level 1: 0.60 μg/mL FEU	Level 2: 2.41 μg/mL FEU	Level 3: 5.88 μg/mL FEU
Data Points N	240	240	240
Mean (g/mL FEU)	0.60	2.41	5.88
SD (g/mL FEU)	0.03	0.05	0.08
CV%	5.0%	2.0%	1.4%

Plasma Samples Total Precision

	Level 1: 0.60 μg/mL FEU	Level 2: 2.41 μg/mL FEU	Level 3: 5.88 μg/mL FEU
Data Points N	240	240	80
Mean (g/mL FEU)	0.60	2.41	5.88
SD (g/mL FEU)	0.04	0.07	0.19
CV%	6.2%	2.7%	3.2%

Control Samples Within Run Precision

	Level 1: 0.97 μg/mL FEU	Level 2: 2.99 μg/mL FEU	Level 2: 7.47 μg/mL FEU
Data Points N	240	240	240
Mean (g/mL FEU)	0.97	2.99	7.47
SD (g/mL FEU)	0.03	0.05	0.11
CV%	2.9%	1.6%	1.4%

Control Samples Total Precision

	Level 1: 0.97 μg/mL FEU	Level 2: 2.99 μg/mL FEU	Level 2: 7.47 μg/mL FEU
Data Points N	240	240	240
Mean (g/mL FEU)	0.97	2.99	7.47
SD (g/mL FEU)	0.04	0.08	0.27
CV%	4.4%	2.8%	3.6%

External Study

The precision of the Diazyme D-Dimer Assay was also evaluated at three external sites by intended users. In the study, four different patient samples of citrated plasma containing 0.36 μg/mL, 1.06 μg/mL, 3.53 μg/mL and 7.20 μg/mL FEU respectively, were tested in duplicates with 2 runs per day over 5 nonconsecutive working days using three lots of reagent, three lots of calibrators, three different clinical testing sites, three different operators and three different instruments. The results are shown below:

Sample	within run	between run	between day	between lot	total	Mean μg/mL FEU
	CV%	CV%	CV%	CV%	CV%	
1	8.9%	8.3%	7.6%	7.1%	11.5%	0.36
2	3.8%	3.6%	7.4%	8.3%	8.3%	1.06
3	2.9%	3.9%	3.1%	0.7%	4.7%	3.53
4	1.6%	3.1%	2.4%	1.5%	3.5%	7.20

LOB, LOD, and LOQ

The LOB, LOD, LOQ of the Diazyme D-Dimer Assay was determined according to CLSI EP17-A. LOB was determined to be 0.06 μg/mL FEU; LOD was determined to be 0.09 μg/mL FEU. To determine LOQ, specimens with mean measured concentrations ranging from 0.02 to 0.93 were assayed. Based on the EP evaluator-8 fitted model, the LOQ (lowest concentration for which CV is less than a target of 20%) is 0.15 μg/mL FEU.

Linearity

Eleven levels of the D-Dimer linearity set were prepared by diluting a specimen containing 8.0 μg/mL FEU with saline according to Clinical and Laboratory Standards Institute EP6-A and tested on Modular P. Diazyme D-Dimer assay is linear from 0.15 to 8.0 μg/mL FEU.

Method Comparison

To demonstrate accuracy, the Diazyme D-Dimer Assay was evaluated by testing individual citrated plasma from the intended target population (Intensive Care Unit, Obstetrics, Trauma, Post-Operative and Operating Room) with comparison to a legally marketed D-Dimer device at the manufacturer site and two external clinical laboratories. A total of 128 citrated plasma samples (88 unique samples) with D-Dimer ranging from 0.17 to 7.95 μg/mL FEU were compared. Repeat testing was addressed by bootstrapped regression analysis with stratification is shown below:

Parameter	**Total of 3 sites**
Slope	0.979
95% CI	0.909 to 1.060
Intercept	-0.106
95% CI	-0.260 to 0.026
R^2	0.939

The bias around the medical decision point is -0.12 μg/ml FEU

Interference
The following substances do not interfere with this assay at the levels tested (less than 10% bias):

Hemoglobin:	up to 500 mg/dL
Bilirubin:	up to 40 mg/dL
Bilirubin Conjugated:	up to 40 mg/dL
Triglycerides:	up to 1000 mg/dL
Ascorbic acid:	up to 176 mg/dL
Rheumatoid Factor	up to 100 IU/mL
Heparin	up to 1.5 IU/mL
HAMA	up to 490 ng/mL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Diazyme Laboratories
c/o Dr. Abhijit Datta
12889 Gregg Court
Poway, CA 92064

Jan 24, 2013

Re: k112120
Trade/Device Name: Diazyme D-Dimer Assay Kit, Diazyme D-Dimer Assay Control Set and Diazyme D-Dimer Assay Calibrator Set
Regulation Number: 21 CFR §864.7320
Regulation Name: Fibrinogen/fibrin degradation products assay
Regulatory Class: Class II
Product Code: GHH, DAP, JIT
Dated: January 17, 2013
Received: January 18, 2013

Dear Dr. Datta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (If Known): K112120

Device Name: Diazyme D-Dimer Assay Kit, Diazyme D-Dimer Assay Calibrator Set, Diazyme D-Dimer Assay Control Set.

Indications for Use:

The D-Dimer Assay is for the quantitative determination of fibrinogen/fibrin degradation products (D-Dimer) in human plasma. Measurement of D-Dimer is used as an aid in detecting the presence of intravascular coagulation and fibrinolysis. For in vitro diagnostic use only.

The Diayzme D-Dimer Assay Calibrator Set is intended for use in the calibration of the D-Dimer assay only. For *in vitro* diagnostic use only.

The Diazyme D-Dimer Assay Control Set is intended for use as quality controls for the Diazyme D-Dimer assay only. For *in vitro* diagnostic use only.

Prescription Use X AND/Or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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